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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

JONES, DAMERON L.

ART UNIT PAPER NUMBER

1616

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/779,693

**Applicant(s)**

ROTHBARD ET AL.

**Examiner**

D. L. Jones

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 September 2004 and 10 May 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 32-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32,33 and 40 is/are rejected.
- 7) ☒ Claim(s) 34-39 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the acceptable RCE filed 9/17/04. In addition, the after final amendment filed 5/10/04 is acknowledged wherein claims 1-31 are cancelled and claim 32 is amended.

**Note:** Claims 32-40 are pending.

## **RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENT**

2. Applicant's arguments/amendment filed 5/10/04 to the rejection of claims 32, 33, and 40 made by the Examiner under 35 USC 102 and 103 have been fully considered and deemed persuasive for reasons of record. Thus, all outstanding rejections are hereby WITHDRAWN because Applicant has amended the claims to overcome the rejections.

## **NEW GROUNDS OF REJECTIONS**

### **Double Patenting**

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

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1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 32 and 40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, and 7 of U.S. Patent No. 6,730,293. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compositions comprising a biologically active agent and a transporter having amidino moieties. The claims differ in that the patented claims are directed to specific biologically active agents and a transporter that has 5-25 amidino residues. However, it would be obvious to a skilled practitioner in the art that the instant invention encompasses that of the patented invention since both are directed to compositions wherein a biologically active agent and transporter having amidino groups must be present.

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5. Claims 32, 33, and 40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 106 and 116-121 of U.S. Patent No. 6,593,292. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compositions comprising a biologically active agent and a transporter having amidino moieties. The claims differ in that the patented claims are directed a transporter that has 5-25 amidino residues. However, it would be obvious to a skilled practitioner in the art that the instant invention encompasses that of the patented invention since both are directed to compositions wherein a biologically active agent and transporter having amidino groups must be present.

#### **103(a) Rejections**

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 32, 33, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz et al (US Patent No. 5,716,614).

**Katz et al** disclose a method of delivering a biologically active agent to a target wherein a complex comprising the biologically active agent and a polycationic carrier are utilized. The polycationic carrier may be polylysine, polyarginine, or polyornithine having 5-50 amino acid residues (see entire document, especially, abstract). In

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addition, Katz et al disclose that the conjugates/complexes are capable of transporting the therapeutic, prophylactic, or diagnostic agent to the desired target (column 4, lines 59-68; column 5, lines 61-65). The complex/conjugate may be held together by Van der Waal's and electrostatic forces or by covalent bonding (column 5, lines 15-17).

The biologically active agent may be hormones, proteins, peptides, DNA, RNA, as well as biological vectors (column 5, lines 26-35). The invention is useful for delivering active agents such as anti-neoplastic agents, anti-microbial agents, anti-parasitic agents, adrenergic agents, catecholaminergic agents, anti-convulsants, nucleotide analogues, anti-trauma agents, enzymes, and proteins (column 10, lines 58-68). Katz et al fail to disclose an example wherein the complex is not covalently linked.

Applicant's newly amended claims disclose that the biologically active agent and the transporter are non-covalently linked. It would have been obvious to one of ordinary skill in the art at the time the invention was made that the biologically active agent and transporter form a non-covalent bound complex because column 5, lines 15-17, it is disclosed that the complex/conjugate may be held together by Van der Waal's and electrostatic interactions or by covalent bonds. Thus, the skilled practitioner in the art would recognize that non-covalent bonding between the components of the complex/conjugate is possible.

#### **CLAIM OBJECTIONS**

8. Claims 34-39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


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**Note:** These claims are allowable over the prior art of record for reasons already of record.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
D. L. Jones  
Primary Examiner  
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December 13, 2004